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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,781	10/27/2000	Renc S. Hubert	G&C 129.23-US-U1	6670

7590            04/30/2002

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[REDACTED] EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 04/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/698,781	HUBERT ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Stephen L. Rawlings, Ph.D.	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-38 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input checked="" type="checkbox"/> Other: <i>Election facsimile cover sheet</i> . |

## **DETAILED ACTION**

1. Claims 1-38 are pending in the application and are currently subject to a restriction and election requirement.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-8 and 10-14, insofar as the claims are drawn to a method comprising detecting the presence, or measuring the level of a polypeptide in biologic samples, classified in class 435, subclass 7.23.

Group II. Claims 5-9, insofar as the claims are drawn to a method comprising detecting the presence, or measuring the level of a mRNA molecule in biologic samples, classified in class 435, subclass 6.

Group III. Claims 15, 36, and 38, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding an antibody, or a fragment or derivative thereof and a method for treating a patient comprising administering to the patient said pharmaceutical composition, classified in class 514, subclass 44.

Group IV. Claims 16-19, 34, 35, and 37, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding a polypeptide or fragment thereof and a method for treating a patient comprising administering to the patient said pharmaceutical composition, classified in class 514, subclass 44.

Group V. Claims 20, 21, 32, and 33, drawn to a pharmaceutical composition comprising a polypeptide or a fragment thereof, classified in class 424, subclass 277.1.

Group VI. Claims 22-31, drawn to a pharmaceutical composition comprising an antibody, or a fragment or derivative thereof, classified in class 424, subclass 138.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions in groups III-VI are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in groups I-VI are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

The inventions in groups I and II and groups III-VI are not at all related because the products of groups III-VI are not specifically used in any of the steps of the claimed methods in groups I and II.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application is further subject to a requirement to elect a species of invention encompassed by the claims. Claims 18, 32, and 34 are generic.

Claim 18 is generic to a plurality of disclosed patentably distinct species comprising pharmaceutical compositions comprising a polynucleotide encoding a polypeptide, wherein said polypeptide comprises an amino acid sequence selected from the group consisting of (a) SEQ ID NO: 8, (b) SLK, (c) SEQ ID NO: 9, (d) SEQ ID NO: 10, (e) SEQ ID NO: 11, (f) SEQ ID NO: 12, (g) SEQ ID NO: 13, (h) SEQ ID NO: 14, (i) SEQ ID NO: 15, (c) SEQ ID NO: 16, (c) SEQ ID NO: 17, (c) SEQ ID NO: 18, (c) SEQ ID

NO: 19, (j) SEQ ID NO: 20, (k) SEQ ID NO: 21, (l) SEQ ID NO: 22, (m) SEQ ID NO: 23, (n) SEQ ID NO: 24, (o) SEQ ID NO: 25, and (p) SEQ ID NO: 26. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (a)-(p), even though this requirement is traversed.

Claim 32 is generic to a plurality of disclosed patentably distinct species comprising vaccine compositions comprising an immunogenic portion, wherein said immunogenic portion comprises an amino acid sequence selected from the group consisting of (a) SEQ ID NO: 17, (b) SEQ ID NO: 18, (c) SEQ ID NO: 19, (d) SEQ ID NO: 20, (e) SEQ ID NO: 21, (f) SEQ ID NO: 22, (g) SEQ ID NO: 23, (h) SEQ ID NO: 24, (i) SEQ ID NO: 25, and (j) SEQ ID NO: 26. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (a)-(j), even though this requirement is traversed.

Claim 34 is generic to a plurality of disclosed patentably distinct species comprising vaccine compositions comprising a polynucleotide encoding an immunogenic portion, wherein said immunogenic portion comprises an amino acid sequence selected from the group consisting of (a) SEQ ID NO: 17, (b) SEQ ID NO: 18, (c) SEQ ID NO: 19, (d) SEQ ID NO: 20, (e) SEQ ID NO: 21, (f) SEQ ID NO: 22, (g) SEQ ID NO: 23, (h) SEQ ID NO: 24, (i) SEQ ID NO: 25, and (j) SEQ ID NO: 26. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (a)-(j), even though this requirement is traversed.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642



DONNA WORTMAN  
PRIMARY EXAMINER

slr

April 26, 2002



# RESTRICTION/ELECTION FACSIMILE TRANSMISSION

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